K131166

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AUG 2 2013

510(k) SUMMARY

Date Prepared: July 29, 2013

Type of Test: Qualitative fluorescent hCG immunoassay

Applicant:

Quidel Corporation
10165 McKellar Court
San Diego, California 92121
Telephone: 858-552-7908
Fax: 858-646-8045

Submission Contact: John D. Tamerius, Ph.D.

Proprietary and Established Names: Sofia® hCG FIA

Device Classification:

Product Code:	JHI
Classification:	Class II
Regulatory Section:	21 CFR 862.1155(a), Human Chorionic Gonadotropin (HCG) test system intended for the early detection of pregnancy
Panel:	Clinical Chemistry (75)

Intended Use:

The Sofia hCG FIA is an immunofluorescence-based lateral flow assay intended for the qualitative detection of human Chorionic Gonadotropin (hCG) in urine specimens and is designed to aid early detection of pregnancy.

The test is intended for prescription use only, including use at point-of-care sites.

Device Description:

The test kit consists of individually packaged test Cassettes—each containing monoclonal murine antibodies for the capture and detection of hCG; disposable specimen transfer pipettes; and a package insert. The test is a qualitative immunofluorescence-based assay used to detect concentrations of 20 mIU/mL hCG or more in urine.

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Comparison with Predicate:

Item	Proposed Device	Predicate Device
Features	**Sofia hCG FIA**	**QuickVue+ One-Step hCG Combo test (K973858)**
Intended Use	The Sofia hCG FIA is an immunofluorescence-based lateral flow assay intended for the qualitative detection of human Chorionic Gonadotropin (hCG) in urine specimens and is designed to aid early detection of pregnancy. The test is intended for prescription use only, including use at point-of-care sites.	The QuickVue+ One-Step hCG Combo test is a one-step immunoassay intended for the qualitative detection of human Chorionic Gonadotropin (hCG) in serum or urine for the early detection of pregnancy. The test is intended for use by healthcare professionals.
Specimen Type	Urine	Urine/Serum
Format	Cassette	Cassette
Test Principle	Immunofluorescence-based lateral flow assay	Lateral flow immunoassay
Instrument	Sofia Analyzer	No instrument; visually-read assay
Read Result Time	Approximately 3 minutes	3 minutes for urine
Analytical Sensitivity	20 mIU/mL for urine	20 mIU/mL for urine
Traceability	WHO International Standard 4th Edition 75/589	WHO International Standard 3rd Edition 75/537
Storage	15 to 30°C	15 to 30°C

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Test Principle:

The Sofia hCG FIA is an immunofluorescence-based lateral flow test for use with the Sofia Analyzer. The test uses a pair of monoclonal murine antibodies specific to the beta subunit of hCG to capture and detect hCG. The beta subunit was chosen to ensure specificity as the alpha subunit is nearly identical to the alpha subunit found in LH, FSH and TSH.

To perform the test, a urine specimen is collected and dispensed into the Sample Well on the Test Cassette. The Cassette is placed inside of the Sofia Analyzer for an automatically defined development time. The Sofia Analyzer then scans the test strip and analyzes the fluorescent signal, using method-specific algorithms. The Sofia Analyzer then displays the test result (Positive, Negative, or Invalid) on the screen, and optionally prints the results on an integrated printer.

Summary of Performance Data:

Numerous studies were undertaken to document the performance characteristics and substantial equivalence of the test to the predicate device. These studies included the following:

a. Analytical Performance

1) Reproducibility

The reproducibility of the Sofia hCG FIA was evaluated at three (3) different laboratories. Three (3) different operators at each site tested a series of coded, contrived samples, prepared in negative urine, ranging from a low negative (5 mIU/mL) to a moderate positive (25 mIU/mL) hCG. For each level a total of 90 replicates were tested over five (5) different days at each site. The results at each site agreed 100% with the expected results for these levels. There were no significant differences observed within run, between runs, or between sites.

2) High Dose Hook Effect

A high dose hook effect study was performed by spiking high levels of hCG concentrations 0 to 500,000 mIU/mL into negative urine and evaluating the test results. Positive results were observed up to 500,000 mIU/mL hCG. Therefore no hook effect was observed for urine samples with hCG concentrations up to 500,000 mIU/mL.

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3) Detection Limit

The sensitivity of the device was tested by spiking pooled male urine with varying concentrations (0 to 100 mIU/mL) of hCG traceable to WHO International 4th Standard. The positive/negative threshold at which 100% of the samples tested positive was confirmed at 20 mIU/mL hCG.

4) Analytical Specificity

Interference and cross-reactivity studies were performed by adding known amounts of chemical substances, urine analytes, hormones, and microorganisms to pooled negative urine. No cross-reactivity or interference was observed for the substances and microorganisms listed below:

Item	Substance/Microorganism	Concentration
Chemical Substances		
1	Acetaminophen	20 mg/dL
2	Acetoacetic Acid	1,600 mg/dL
3	Acetylsalicylic Acid	20 mg/dL
4	Ampicillin	2 mg/dL
5	Ascorbic Acid	20 mg/dL
6	Atropine	20 mg/dL
7	β-Hydroxybutyrate	2,000 mg/dL
8	Benzoylecgonine	8 mg/dL
9	Bovine Serum	10 mg/dL
10	Caffeine	20 mg/dL
11	Cannabinol	10 mg/dL
12	Cellulose	500 mg/dL
13	Citric Acid	500 mg/dL
14	Clomiphene	100 mg/dL
15	Cow's Milk	9 mg/dL
16	DMSO	0.90%
17	EDTA	80 mg/dL
18	Ephedrine	18 mg/dL
19	Ethanol	0.80%
20	Gentisic Acid	20 mg/dL
21	Methanol	0.90%
22	Phenothiazine	20 mg/dL
23	Phenylpropanolamine	20 mg/dL
24	Salicylic Acid	20 mg/dL
25	Tetracycline	20 mg/dL
26	Theophylline	20 mg/mL
27	Uric Acid	18 mg/dL
Urine Substances		
28	Albumin (serum)	2,000 mg/dL
29	Bilirubin	1 mg/dL

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Item	Substance/Microorganism	Concentration
30	Glucose	2,000 mg/dL
31	Haptoglobin	1 mg/dL
32	Hemoglobin	1 mg/dL
33	Human Anti-Mouse Antibodies	2.85 ng/mL
34	Myoglobin	1 mg/dL
35	Rheumatoid Factor	1.08 IU/mL
36	Serum (negative human)	1%
37	Urine Peroxide	10 mg/dL
38	Urine pH	5–9
39	Urine Specific Gravity	1.005-1.037
	Hormones	
40	hLH	450 mIU/mL
41	hFSH	900 mIU/mL
42	hTSH	1,000 mIU/mL
43	Estriol 17-beta	28,000 µg/dL
44	Pregnanediol glucuronide	45,000 µg/dL
45	β-core fragment, hCG	5.1×10^5 pmol/L
	Microorganisms	
46	*Escherichia coli*	2.61×10^8 CFU/mL
47	*Streptococcus agalactiae* (Group B)	2.50×10^7 CFU/mL
48	*Chlamydia trachomatis*	1×10^7 IFU/mL
49	*Candida albicans*	1.07×10^7 CFU/mL

b. Clinical Performance:

A multi-center clinical study was conducted to establish the performance of the Sofia hCG FIA compared to results obtained from another commercially available qualitative test. This study was conducted by health care personnel at five (5) distinct sites in various geographical regions within the United States. In this multi-center, point-of-care (POC) field trial, 974 fresh urine specimens, collected from patients presenting for pregnancy testing, were evaluated.

Sofia hCG FIA Performance Compared to a Commercially Available Qualitative Test

	Comparator Test	
	Pos	Neg
Sofia Pos	176	2
Sofia Neg	1	795
Total	177	797

Positive Agreement = >99% (176/177) (95% CI=97-100%)

Negative Agreement = >99% (795/797) (95% CI=99-100%)

Overall Agreement = >99% (971/974) (95% CI=99-100%)

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Conclusion:

These studies demonstrated the substantial equivalence of the Sofia hCG FIA for use with the Sofia Analyzer to the existing product already marketed, QuickVue+ One-Step hCG Combo test, K973858. They further demonstrated the suitability of the product for point-of-care use. Such studies are a critical element in establishing the fundamental safety and effectiveness of the product and its appropriateness for commercial distribution.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Quidel Corp.
C/O John D. Tamerius
10165 McKellar Ct.
SAN DIEGO CA 92121

August 2, 2013

Re: K131166
Trade/Device Name: Sofia® hCG FIA
Regulation Number: 21 CFR 862.1155
Regulation Name: Human chorionic gonadotropin (HCG) test system
Regulatory Class: II
Product Code: JHI
Dated: July 1, 2013
Received: July 3, 2013

Dear Dr. Tamerius:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for

the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Katherine Serrano -S

For: Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K131166

Device Name: Sofia® hCG FIA

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The Sofia hCG FIA is an immunofluorescence-based lateral flow assay intended for the qualitative detection of human Chorionic Gonadotropin (hCG) in urine specimens and is designed to aid early detection of pregnancy.

The test is intended for prescription use only, including use at point-of-care sites.

Prescription Use (Part 21 CFR 801 Subpart D)	X	AND/OR	Over-The-Counter Use (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Denise Johnson-Iyles -S
2013.08.01 08:31:34 -04'00'

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

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